K972676

COMBACT DIAGNOSTIC SYSTEMS LTD

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FEB 23 1998

combact

510(k) Summary: Substantial Equivalence

- **Device name** *Bactis 160US*
- **Common name** Urine screening device
- **Classification name** Kit, Screening Urine .
- **510(k) submitter** Combact Diagnostic Systems Ltd.,
  Medinat Hayehudim 60, P.O.B 2222,
  Herzliya, Israel 46120.
  Phone: 972-9-9561412
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- **Device classification** The device is a class I device
- **Predicate Device:** The *Bactis 160US* is substantially equivalent to the Bac-T-Screen, BioMerieux- Vitek Inc. 1993 (K924218)

1.1 Intended Use

The ***Bactis 160US*** is an automated, computer assisted, optical imaging system intended for rapid screening analysis of urine samples for presence of bacteria.

1.2 Device Description

The *Bactis 160US* is based on direct screening of urine using optical image analysis. Thirty (30) µl of well-mixed urine is mixed with fluorescent stains that bind to bacteria and other particles present in the specimen. The stained samples are filtered through a membrane. The dispersed and stained organisms are excited with a filtered lamp to produce a distinct fluorescent signal. Using fluorescence microscopy and a CCD camera the image of the sample is captured. These microscopic images are then analyzed. Using digitized image processing techniques, the bacteria are localized and enumerated, and their concentration is determined. Bacterial concentration for each specimen can be then reported. Alternatively, the concentration can be compared to a predetermined threshold (according to each laboratory's policy) and each urine sample can be categorized according to the

infection category of "positive" or "negative". This method provide results within 25 minutes.

The *Bactis* system is comprised of the following main components:

1. Control and Data Management System (CMS)
2. Specimen Processor and Analyzer - (SP&A) Unit

The urine screening process is controlled and monitored by the operator via the CMS, The CMS is comprised of two PC computers. An optional printer can be used to provide diagnostic reports. In the SP&A Unit, the specimens are processed and analyzed.

1.2.1 Functional Description

The *Bactis 160US* testing process is performed as follows:

The specimens are identified by a bar-code reader which is connected to the CMS computer (or by manual logging of the specimens' identification parameters into the computer) and loaded in their standard collection containers into a portable tray that can accommodate up to 16 specimens.

The portable tray is inserted by the operator into the SP&A unit's Input Station.

Aliquots of each sample are automatically dispensed by the robotic arm into special multi-well cassettes. Fluorescent stains are added and the cassette is directed to the filtration station. Each sample is filtered through a membrane, and the liquid is discarded. This process produces a monolayer of homogeneously dispersed and stained organisms.

The samples are then directed to the microscopic imaging station where the system detects the presence of organisms. Bacterial concentration is reported for each specimen.

1.3 Substantial Equivalence Comparison

The intended/indications for use of the *Bactis 160 US* are similar to other legally marketed types of urine screening devices. The *Bactis 160 US* is an automated, computer assisted, microscopy system intended for detection and enumeration of bacteria in urine specimens. The device is indicated for use in rapid screening analysis of urine samples to assess the occurrence of bacteriuria.

There are several methods or technological applications currently in use for urine screening for detection of bacteriuria. In general, urine screening devices for bacteriuria are based on bacterial growth such as the standard culture, or on direct enumeration of bacteria in urine samples. Both the *Bactis 160 US* and the legally marketed Bac-T-Screen 2000 (K924218) devices can detect and enumerate bacteria directly in urine samples without first requiring culture of the urine specimen. The technology employed by the *Bactis 160 US* is similar to the Bac-T-Screen 2000 in that urine samples are filtered and stained with proprietary stains before the enumeration process takes place. However, the *Bactis 160 US*, unlike the Bac-T-Screen 2000 (which is based on a colorimetric measurement), employs a direct bacterial particle counting technique, which yields accurate and reliable enumeration of bacteria in urine.

Table 1 presents the salient similarities and differences of devices/ methods used for urine screening.

Table 1 Similarities and Differences			
Comparison Elements	***Bactis 160 US***	**Bac-T-Screen**	**Standard Culture**
Intended Use	Bacteriuria detection	Bacteriuria/Pyuria detection	Bacteriuria detection
Requires growth of the organism	No	No	Yes
Technology/Methodology	Direct bacterial detection and enumeration via fluorescent staining, filtration, and optical imaging	Direct bacterial detection via filtration, staining, colorimetric analysis.	Bacterial growth and enumeration of formed colonies on agar plates.
Time of analysis	25 min.	2 min.	"overnight"
Threshold of positivity	10^5 CFU/ml	10^5 CFU	Site established thresholds (10^4- 10^5)
Objective interpretation of results (automated reader/analyzer)	Yes	Yes	Mostly read "manually" Automated colony counters available.
Automated addition of reagents to sample	Yes	Yes	N/A
Enumeration	Yes	No	Yes
Min. vol. of urine required	1 ml	1 ml	0.1 ml

1.4 Performance Comparison

Performance data collected during clinical studies conducted at two sites, demonstrated that the *Bactis 160 US* can detect bacteria in urine samples and report bacterial concentration as well as the standard reference procedures. In addition, the clinical studies included a more detailed protocol for assessing bacteriuria such as expanded culture conditions, Gram staining, and tests to detect the presence of growth inhibitory substances in urine, e.g., antimicrobic agents.

A total of 4561 random urine specimens were prospectively tested at two different clinical sites under double blinded conditions. Appropriate statistical techniques were applied to demonstrate equivalence of methods. The clinical studies support the comparative safety and effectiveness of the *Bactis 160 US* to standard reference culture methods for detecting

bacteriuria. Table 2 presents the (lowest/highest) values of indicators of performance obtained for the *Bactis 160 US.*

Table 2: Performance data result	
	Bactis 160US
Sample size	4561
Threshold CFU/ml	$\geq 10^5$
Sensitivity	87.5 - 90.2%
Specificity	75% - 86.7%
Negative Predictive Value	96.2 - 97.5%

1.5 Conclusions

Based on all the information presented in the 510(k) submission it was concluded that there is both a scientific as well as regulatory basis for determining the *Bactis 160 US* Substantially Equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Thomas M. Tsakeris
Devices and Diagnostics Consulting Group &
U.S. Contact for Combact Diagnostics, Inc.
16809 Briardale Road
Rockville, MD 20855

FEB 23 1998

Re: K972676
Trade Name: Urine Screening Device
Regulatory Class: I
Product Code: JXA
Dated: November 24, 1997
Received: November 25, 1997

Dear Mr. Tsakeris:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html"

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

2. Intended Use/ Indication for Use Statement

510(k) Number (if Known) K972676

Device Name: *Bactis 160US*

2.1 Intended Use

The *Bactis 160US* is an automated, computer assisted, optically based *in vitro* diagnostic instrument intended for the rapid detection and enumeration of bacteria in urine specimens. Urine samples are stained, filtered through a membrane, and excited with light of a defined wavelength range so as to produce a distinct fluorescent signal. Using fluorescent microscopy and a CCD camera, the image of the sample is captured. Using digitized image processing, the microscopic images are analyzed and the concentration of bacteria present in the specimen is determined by applying a proprietary software algorithm.

2.2 Indication for Use

The *Bactis 160US* is indicated for rapid urine screening for the purpose of determining the occurrence of bacteriuria. Evidence of bacteriuria is an important factor for clinicians to consider in making a diagnosis of urinary tract infection.

2/23/98

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K972676

Prescription Use ✓ OR Over-The Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)